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Application No. 10/677,694  
Docket No. IB-8 (A4-1770)  
Amendment dated June 6, 2007  
Reply to Office Action of February 8, 2007

**Amendments to the Drawings:**

The attached two (2) sheets of drawings include changes to Figure 6 and present new Figures 7 and 8. These sheets, which include Figures 5-8, replace the original drawing sheet that included Figure 5. Figures 6, 7, and 8 depict block diagrams showing three embodiments for the closed-loop pacing/ICD tuning system described in the first full paragraph on page 11 of the specification.

Attachment(s): Replacement Sheet(s) (2)

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### REMARKS

As of the filing of the present Office Action, claims 1-14, 17-31, 33-44, 46-58, 60-63, and 65-72 were pending in the above-identified US Patent Application. In the Office Action, the Examiner objected to the specification, drawings, claims, and new matter, rejected all pending claims but claim 31 under 35 USC §112, first paragraph, rejected claims 1, 3, 5, 6, 9, 11, 12, 17, 19, 21, 23, 25, 27, 29, 37, 38, 41-44, 46-48, 60, 69, and 70 under 35 USC §103, cited claims 2, 4, 7, 8, 10, 13, 14, 18, 20, 22, 24, 26, 28, 30, 33-36, 39, 40, 49-56, 58, 61-63, 65-68, and 71 as potentially reciting allowable subject matter, and allowed claim 31.<sup>1</sup>

In response to the above, Applicants have amended the specification, drawings, and claims as set forth above. More particularly:

The specification has been amended at pages 5 and 11 to refer to new Figures 6, 7 and 8, which schematically and separately depict different embodiments disclosed on page 11 and originally recited in claims 60-68 as filed without going beyond the original scope of the specification and claims.

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<sup>1</sup> Though claim 72 was not included in the list of claims under the heading "Allowable Subject Matter," it depends from claim 71 and was not identified under any prior art rejection. Therefore, Applicants believe claim 72 was intended to be included in the list of potentially allowable claims.

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Independent claim 1 has been amended to cancel the limitations previously incorporated from its dependent claims 59-62, and to incorporate the limitations from its dependent claims 42 and 43.

Independent claim 2 has been amended to use the term "pacing/ICD unit" instead of "patient pacemaker" and the term "readout device" instead of "external reader."

In view of the amendments to their parent claim 1, dependent claims 41-43, 46, and 47 have been canceled without prejudice, and dependent claims 44 and 48 have been amended to depend directly from claim 1 and provide consistency with amended claim 1.

Finally, dependent claims 48 and 56 have been amended to address a grammatical matter.

Applicants respectfully believe that the above amendments do not present new matter, and request favorable reconsideration and allowance of remaining claims 1-14, 17-31, 33-40, 44, 48-58, 60-63, and 65-72 in view of the above amendments and the following comments.

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### **Objections Regarding New Matter, Drawings, and Specification**

These objections arise from confusion caused by the use of less than strictly consistent terminology in the application.<sup>2</sup> Amendments to the specification presented in Applicants' amendment of February 2, 2006, were intended to address these inconsistencies. In the specification as filed, the "reader unit" originally introduced in the "Summary of the Invention" at line 20 of page 3 and used again at line 6 of page 11, was also identified in the specification, claims, and abstract by not less than six other names: "external reader" (including the "external reader 104" of Figure 2 and the "external reader 202" of Figure 3), "reader" and "reader device" (including the "reader 202" and "reader device 202" of Figure 3), "readout unit" (page 10), and "non-implantable readout device" (claims and Abstract). Again, these inconsistencies were thought to have been already addressed in Applicants' amendment of February 2, 2006.

All of the above terms include the word "read," and when taken in context Applicants believe that one of ordinary skill in the art would readily understand that all of these terms refer to the same thing. Therefore,

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<sup>2</sup> Applicants filed the application *pro se*.

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Applicants believe that it is entirely compatible within the application and not new matter to identify the "intermediate reader unit" and "external reader" discussed in the first full paragraph of page 11 as the "external reader 104" of Figure 2 and the "external reader 202" of Figure 3 (as done in new Figures 6, 7, and 8), since "external reader," "reader," "reader device," "reader unit," and "readout unit" have been used interchangeably in the application, and all of these terms are within the scope of the term "non-implantable readout device" originally and currently used in the claims and abstract.

The present Office Action also states that the specification fails to mention reference numbers 106 and 107 of Figure 6, and fails to provide a description of Figure 6. However, these were inserted by amendments requested at pages 4 and 11 of Applicants' amendment filed February 2, 2006.

Applicants believe the above issues are further addressed with revised Figure 6 and new Figures 7 and 8, which Applicants believe more precisely correspond to the disclosure at page 11 of the specification. The four embodiments covered by Figures 6, 7, and 8 (the "power unit" 107 of Figure 6 is optional) are clearly identified by the amendments to the specification, which has been amended to specifically cite the appropriate

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Figure with the description of its corresponding embodiment.

Applicants believe that the above amendments and remarks overcome the objections concerning new matter, the drawings, and the specification, and therefore respectfully request their withdrawal.

### **Objections to the Claims**

The Examiner objected to claims 1, 2, 43, 47, and 55.

Claims 1 and 2 were objected to for using the term "patient pacemaker" instead of "pacing-ICD unit." This objection is believed to be overcome by the amendments to claims 1 and 2. The terms are no longer present in claim 1, and claim 2 has been amended in accordance with the Examiner's suggestion, though without the effect of narrowing the scope of claims 1 and 2 in view of the discussion of the pacing-ICD unit and pacemaker at page 11 of the specification.

Claim 43 (now canceled) was objected to for using the term "the portion" instead of "a portion." However, "the portion" found antecedent basis in its parent claim 1 ("a portion of said anchoring mechanism passes through a septum of the heart").

In claims 47 (now canceled) and claim 55, the Examiner suggested

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the term "trabeculate" or "trabecular" instead of "trabeculated." However, Applicants respectfully believe that the proper term is "trabeculated" because it is used as an adjective and not a verb or noun. Applicants' use of "trabeculated" is also consistent with industry usage, as evidenced from the following excerpt from Wikipedia:

The right auricle, along with the right atrial body, is lined with pectinate muscles that form a network of hills and furrows that give it a trabeculated surface.

*Wikipedia, Right auricular appendix,*  
[http://en.wikipedia.org/wiki/Right\\_auricular\\_appendix](http://en.wikipedia.org/wiki/Right_auricular_appendix) (as of May 31, 2007, 16:37 GMT).

In view of the above, Applicants respectfully request withdrawal of the objections to the claims.

**Claim Rejections under 35 USC §112, First Paragraph**

Claims 1-14, 17-30, 35-44, 46-58, 60-63, and 65-72 were rejected under 35 USC §112, first paragraph, as failing to comply with the enablement requirement. Briefly, the rejection appears to be based on the recitation in independent claims 1 and 2 of a "non-implantable readout device" capable of (in claim 1) "at least one of electromagnetic telecommunication and

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electromagnetic wireless powering" or (in claim 2) "electromagnetic telecommunication and electromagnetic wireless powering," while also reciting an "external unit" and a "reader." The Examiner acknowledged a passage on page 11 of the specification, but concluded that this passage fails to address a system having a "non-implantable readout device," an "external unit," and a "reader," and concluded

The specification fails to clearly explain how to make or use a system that includes non-implantable readout device, as claimed, in combination with any of the pacing/ICD unit, external unit, or external reader, such that one of ordinary skill in the art would be unable to make and/or use the claimed system without undue experimentation, particularly in the case where the non-implantable readout device accomplishes both electromagnetic telecommunication and electromagnet wireless powering of the sensing device. It is unclear why the system would need both the non-implantable readout device and either the external unit or external reader and how all the nonimplantable readout device and external unit ro reader would be used together in the system with respect to each other, the sensor, and the pacing/ICD unit.

Applicants believe that the above concern is addressed in part by Figures 6, 7, and 8, which separately represent embodiments disclosed in the passage at issue on page 11 and recited in original claims 60-68 without going beyond their original scope. The Examiner's concern is also addressed in part



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by the amendments to claim 2, which clarify that the "external reader" is the "readout device," consistent with Applicants' explanation above under the heading "Objections Regarding New Matter, Drawings, and Specification." Finally, as to whether one of ordinary skill in the art would be able to "make and/or use the claimed system without undue experimentation," Applicants note that:

(1) If "said at least one sensing device is directly interrogated by the pacing/ICD unit," the pacing/ICD unit is simply able to provide a functionality of the "readout device," namely, the ability to interrogate the sensing device "without requiring an intermediate reader unit" as originally disclosed on page 11 of the specification. However, such a capability does not eliminate or conflict with the readout device (recited as "allowing electromagnetic telecommunication and electromagnetic wireless powering of said sensing device"), particularly since the readout device is not implanted and may be capable of additional functionalities, including the ability to interface with a display, computer, or other data logging device as described on page 8 of the specification.

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(2) If "said at least one sensing device is interrogated by the pacing/ICD unit" and the system further includes "an external unit solely for transmitting power to said at least one sensing device," the pacing/ICD unit is simply able to provide an interrogation functionality as discussed above, while the "external unit" is able to provide the powering functionality of the readout device. Again, the addition of an external unit capable of providing power to the sensing device does not eliminate or conflict with the use of the readout device.

(3) The situation in which "said at least one sensing device transmits data to said readout device, after which said readout device retransmits data to the pacing/ICD unit" is similar to the first embodiment, but differs by express use of the readout device as an "intermediate reader unit."

The interrogation and powering functionalities are represented in Figures 2 and 3, and are simply shared with the pacing/ICD unit and/or the external unit in the embodiments of Figures 6, 7, and 8.

In view of the above, Applicants respectfully believe that it would not be difficult for one of ordinary skill in the art to make and/or use the claimed system without undue experimentation, and therefore respectfully request withdrawal of the rejection under 35 USC §112.

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### **Rejections under 35 USC §103**

As noted above, independent claim 1 and its dependent claims 3, 5, 6, 9, 11, 12, 17, 19, 21, 23, 25, 27, 29, 37, 38, 41-44, 46-48, 60, 69, and 70 under 35 USC §103. As noted above, Applicants have amended claim 1 to incorporate the limitations of its dependent claims 42 and 43, and therefore now requires that the anchoring mechanism comprises "a portion for passing through a septum of the heart, means adapted for opening on at least one side of the septum, and means adapted for clamping said implantable device to the septum," with the clamping means "comprising said smaller and larger portions of said implantable sensing device."

Though page 10 of the Office Action cites Brockway as disclosing "means 312D for opening on at least one side of the septal wall and adapted for clamping the device to the septal wall," the "expanding deformable stabilizer 312D" cited by the Examiner does not have any clamping capability within the ordinary meaning of the term "clamp."<sup>3</sup> Therefore, Applicants respectfully believe that this limitation of claim 1 is not met, and Applicants

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<sup>3</sup> *Webster's New Twentieth Century Dictionary, Unabridged* (Second Edition), defines the verb "clamp" as "to fasten, strengthen, or brace with a clamp or clamps," and defines the noun "clamp" as "any of various devices for claspings or fastening things together, or for bracing or strengthening parts."

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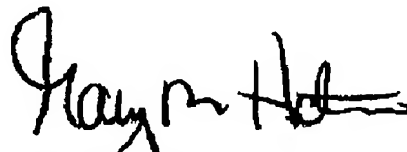
respectfully request withdrawal of the rejections under 35 USC §103 of claim 1  
and its remaining rejected dependent claims.

Closing

In view of the above, Applicants believe that all issues outstanding  
from the Office Action have been addressed, and that the claims define  
patentable novelty over all the references, alone or in combination, of record.  
It is therefore respectfully requested that this patent application be given  
favorable reconsideration.

Should the Examiner have any questions with respect to any matter  
now of record, Applicants' representative may be reached at (219) 462-4999.

Respectfully submitted,



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Attachments: Replacement Drawing Sheets (2); Petition for Extension of Time